510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Terrence J. Sweeney
Vice President, Worldwide Quality and Regulatory Affairs
Advanced Technology Laboratories, Inc.
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7602

Date prepared: April 4, 2001

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

HDI® 5000 Ultrasound System with Assisted Border Detection (ABD,) XRES Imaging, and Panoramic measurement capability

Classification Names

Ultrasonic Pulsed Doppler Imaging System, Product Code 90 IYN, 21 CFR 892.1550

Diagnostic Ultrasonic Scanhead, Product Code 90 ITX, 21 CFR 892.1570

Ultrasonic Pulsed Echo Imaging System, Product Code 90IYO, 21 CFR 892.1560

3) Identification of the predicate or legally marketed device:

Advanced Technology Laboratories, Inc. believes that the Assisted Border Detection (ABD) feature is similar to Agilent's SONOS 5500 Digital Acoustic Quantification feature. XRES Imaging is similar to imaging processing filters currently used on the HDI 5000 system. Panoramic measurement capability is substantially equivalent to the currently marketed Siemens Elegra system with SieScape.

4) Device Description:

The HDI 5000 system is a general purpose, mobile, software-controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and display it on a monitor in 2D, M-mode, 2D Color Doppler, M-mode Color Doppler, Continuous Wave Doppler (CW), Pulsed (PW) Doppler, Color Power Angio (CPA), 3D, or in a combination of modes. The HDI 5000 system also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The HDI 5000 has an output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The HDI 5000 system is designed to accept a large selection of transducers with up to three array transducers and one static probe being connected to the system at any one time. The operator may select among the transducers by means of a control located on the system control panel. All actions affecting the performance of the scanhead are activated from the main system control panel.

Assisted Border Detection (ABD) provides a semi-automated approach for calculating left ventricular volume and ejection fraction (EF.) The goal of the ABD tool is to improve overall study throughput by simplifying the steps required to outline the left ventricular cavity of the heart. The user has the option of either accepting the automated trace and selected image frames or to manually modify the traces as may be necessary for proper alignment.

Measurement capability in Panoramic Imaging allows the user to perform distance or area measurements by using measurement tools currently available on the HDI 5000 system.

XRES Imaging enhances gray-scale image quality by reducing speckle and noise, and enhancing tissue margins and boundaries, while maintaining image resolution and integrity. This feature will operate in real-time and after acquisition while reviewing the multi frame Cineloop® Image.

The HDI 5000 system is designed to accept transducers of the following types and frequency:

frequency range:	2.0 - 10.0 MHz
transducer types:	Linear array
	Curved linear array
	Phased array
	Static probes

Specific operating conditions (frame rate, line density, center frequency, number of

active elements etc.) are automatically optimized by the system software in response to user inputs such as field of view, focal depth, image quality, power etc.

The HDI 5000 system has been designed to meet the following electromechanical safety standards:

- IEC 601-1, International Electrotechnical Commission, Medical Electrical Equipment
- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- CEI/IEC 1157:1992, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- IEC 601-1-2, Collateral Standard: Electromagnetic Compatibility

5) Intended Use:

The HDI 5000 system is intended for ophthalmic, fetal, abdominal, intraoperative, pediatric, small organ, adult and neonatal cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, laparoscopic, and musculoskeletal (conventional and superficial) intended uses as defined in the FDA guidance document.

Typical examinations using the HDI 5000 system are:

- General abdominal and pelvic studies including organ surveys, blood flow assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid/parathyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, and bony structures.
- Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Prostate, prostate biopsy guidance, and rectal wall studies.
- Neonatal head studies.
- Transcranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.
- Cardiac studies in adults and children.
- Monitoring of cardiac function during procedures using transesophageal echocardiography.
- Biopsy guidance for tissue or fluid sampling.
- Assessment of cardiac muscle, coronary arteries and great vessels during cardiac surgery
- Study of myocardial function in adults

- Study of eye anatomy including blood flow in retinal vessels and branches
- Study of the esophagus, stomach, biliary system, pancreas and gastrointestinal tract using endoscopics probe
- Study of abdominal and pelvic organs and masses using laparoscopic probe
- Examination of organs, masses and vessels during surgical procedures
- Study of muscles, ligaments, nerve bundles and connective tissue
- Panoramic imaging showing anatomical relationships over a larger area than that provided by standard 2D ultrasound

6) Technological Characteristics:

This device operates identical to the predicate ultrasound devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D and M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, M-mode, Color Flow, Color M-mode, Color Power Angio, and Pulsed Doppler) are the same as predicate ultrasound devices identified in item 3. Scanhead patient contact materials are biocompatible.

This device conforms to the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM/NEMA, 1992) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

All Applications Other Than Ophthalmic:		
I_{SPTAd}	720 mW/cm2	(Maximum)
TIS/TIB/TIC	0.1 - 6.0	(Range)
Mechanical Index (MI)	1.9	(Maximum)
I_{SPPAd}	0 - 700 W/cm2	(Range)

Ophthalmic Applications:		
I_{SPTAd}	50 mW/cm^2	(Maximum)
TIS at Surface / Thermal Index (TIC)	0.1 - 1.0	(Range)
Mechanical Index (MI)	.23	(Maximum)
I_{SPPAd}	0 - 50 W/cm^2	(Range)

The limits are same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Advanced Technology Laboratories
% Mr. Mark Job
Program Manager
TUV Product Service Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K011224
Trade Name: HDI® 5000 Ultrasound System with Assisted Border Detection(ABD)
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: April 19, 2001
Received: April 20, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following new features intended for use with the HDI® 5000 Ultrasound System, as described in your premarket notification:

- Assisted Border Detection (ABD)
- XRES Imaging
- Measurement Capability in Panoramic Imaging

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good

Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3 INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number:
System: HDI® 5000 Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	P		P	P	P	Note 1	Note 5
Fetal Imaging & Other	Fetal	P	P	P	P	P	Note 1	Notes 2,4, 6, 7
	Abdominal	P	P	P	P	P	Note 1	Notes 2, 4, 7
	Intra-operative (Abdominal, vascular)	P		P	P	P	Note 1	Notes 2, 4, 5
	Intra-operative (Neuro.)	P		P	P	P	Note 1	
	Laparoscopic	P		P	P	P	Note 1	
	Pediatric	P	P	P	P	P	Note 1	Notes 2, 4, 5, 7
	Small Organ (See Note 3)	P	P	P	P	P	Note 1	Notes 2, 4, 5, 7
	Neonatal Cephalic	P	P	P	P	P	Note 1	Note 4
	Adult Cephalic	P	P	P	P	P	Note 1	
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	P	P	P	P	P	Note 1	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 4, 5, 7
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 4, 5, 7
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	
	Cardiac Pediatric	P	P	P	P	P	Note 1	
	Trans-esophageal (card.)	P	P	P	P	P	Note 1	
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note 1	Notes 4, 5, 7
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:
Color Doppler includes Color Amplitude Doppler (previously cleared)
Note 1: PWD/Color Doppler, PWD/Power Doppler (previously cleared)
Note 2: Includes imaging for guidance of biopsy (previously cleared)
Note 3: For example: thyroid, parathyroid, breast, scrotum and penis in adult pediatric and neonatal patients (previously cleared)
Note 4: Color M-mode (previously cleared)
Note 5: Advanced Image Processing a.k.a. SonoCT (previously cleared K991671)
Note 6: Includes infertility monitoring of follicle development (previously cleared)
Note 7: EFOV in B mode includes SonoCT imaging (previously cleared K002003)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011224

SK36